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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/804,408

03/12/2001

Mathew F. Ogle

S16.12-0111

1108

27367 7590 05/30/2007  
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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

05/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/804,408	OGLE ET AL	
	<b>Examiner</b>	<b>Art Unit</b>	
	David M. Naff	1657	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11-28 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-28 and 34-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/19/07 has been entered.

An amendment filed 3/19/07 added new claim 44.

Claims examined on the merits are 1-9, 11-28 and 34-44, which are all claims in the application.

***Claim Rejections - 35 USC § 112***

Claims 1-9, 11-28 and 34-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As set forth in the previous office action of 12/19/06, support is not found in the specification for reciting "the bridges are not glutaraldehyde" in claims 1 and 16, and "the bridge molecules are not glutaraldehyde" in claims 34 and 36. The specification nowhere sets forth that the bridges are not glutaraldehyde. While the specification discloses bridge substances that are not glutaraldehyde, other compounds having the cross-linking function of glutaraldehyde

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are also not included with the specific bridges recited. There is no basis in the specification for only glutaraldehyde being excluded as a bridge because it is not included in the specific bridge materials recited in the specification (pages 19 and 20). To exclude  
5 glutaraldehyde as a bridge, it is suggested the claims be amended to recite a Markush group of the specific bridge compounds recited in the specification.

### ***Response to Arguments***

It is granted as urged in the remarks of the amendment that  
10 negative limitations may be used in claims, the linkers and bridges are chemically different, the linker can be dialdehyde cross-linking agents including glutaraldehyde, and the functional groups of the bridges are generally non-reactive with unmodified tissue or with other bridges. However, this does not establish that the  
15 specification has adequate support for excluding only glutaraldehyde as a bridge when requiring an invention of the scope of claims 1, 16, 34 and 36. There is insufficient basis for excluding only a glutaraldehyde linker as a bridge, and not excluding other disclosed linkers as bridges when the linker is chemically different from the  
20 bridge. Claims 1, 16, 34 and 36 now present a concept of the invention not originally disclosed and supported in the specification.

As recognized by the amendment, MPEP 2173.05(i) discloses that any negative limitation or exclusory proviso must have a basis in the original disclosure. The specification does not have basis for  
25 excluding only glutaraldehyde as a bridge. This is not the same

situation as in the decision disclosed by 194 USPQ 187. This is not a matter of excluding alternatives since glutaraldehyde is not an alternative with respect to bridges. It is an alternative with respect to linkers.

5                   ***Claim Rejections - 35 USC § 103***

Claims 1-9, 11-28 and 34-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle et al (5,958,669) in view of Yang et al (5,935,168) for reasons in the previous office action and for reasons herein.

10           The claims are drawn to tissue containing linkers bonded to tissue and bridge molecules (excluding glutaraldehyde in claims 1-9, 11-28 and 34-43) bonded between two or more of the linkers, to a method of crosslinking tissue to prepare the tissue having linkers and bridge molecules, to tissue containing modified sites having bridge  
15 molecules bonded to two or more of the modified sites, and to a method of crosslinking tissue to prepare the tissue having modified sites and bridge molecules. In all these embodiments, functional groups of the bridges are required to be generally non-reactive with other bridges.

Ogle et al disclose crosslinking tissue to fix tissue by reacting  
20 the tissue with glutaraldehyde.

Yang et al disclose crosslinking tissue with glutaraldehyde, and then reacting with a diamine followed by reacting with additional glutaraldehyde (col 1, line 43 and claims 8-10).

After reacting with glutaraldehyde as disclosed by Ogle et al,  
25 some free aldehyde groups will remain that will react with the diamine

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and result in the glutaraldehyde being a linker and the diamine being a bridge. In this embodiment, glutaraldehyde is not the bridge. The aldehyde groups of glutaraldehyde are generally non-reactive with other aldehyde groups of another glutaraldehyde under certain conditions disclosed by Ogle et al that control self-polymerizing. The amine groups of a diamine will not react with amine groups of another diamine. This will result in a bridge not reacting with another bridge.

#### ***Response to Arguments***

Applicant's arguments filed 3/19/07 have been fully considered but they are not persuasive.

The amendment in the remarks urges that the Ogle et al and Yang et al are directed to preventing calcification of a prosthesis, whereas the present invention is directed to a novel cross-linked tissue, and making cross-linked tissue having strength and flexibility. However, cross-linking as claimed can result in preventing calcification as disclosed by Ogle et al and Yang et al, and tissue cross-linked as disclosed by Ogle et al and Yang et al can have strength and flexibility as tissue cross-linked as claimed.

The amendment urges that there is no factual basis for free aldehyde groups remaining after reaction with glutaraldehyde, and for a diamine reacting with both activated carboxyl groups and free aldehyde groups. However, Ogle et al disclose (col 6, lines 50-55) that since calcification has been associated with unreacted aldehyde groups, a determination of quantities of unreacted aldehyde groups may provide

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some indication of calcification susceptibility. This disclosure indicates that free unreacted aldehyde groups are present. Amine groups reacting with aldehyde groups and carboxyl groups is disclosed by Yang et al (col 6, lines 15-15-24).

5       The amendment incorporates by reference the remarks made in the response 3/24/06. However, these remarks were responded to in the office action of 6/1/06 and were found to be unpersuasive.

**Conclusion**

Any inquiry concerning this communication or earlier

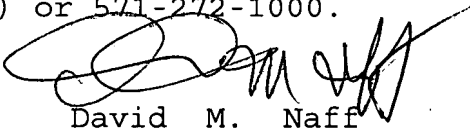
10       communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925.

15       The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David M. Naff  
Primary Examiner  
Art Unit 1657

DMN

15 5/29/07